The Australian Lawful Use of Cannabis Alliance

Submission to:

'Inquiry into Options for Access to Medicinal Cannabis in Exceptional Circumstances'

Victorian Law Reform Commission

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“The arc of History is long, but it bends towards justice.”
Martin Luther King

Written in memory of all the warriors in the battle for cannabis law reform who are now gone.
When freedom in this regard finally comes, may it be your legacy.

18 April 2015

Victorian Law Reform Commission
Level 3
333 Queen Street
Melbourne VIC 3000

The Hon Philip Cummins,

Re: Inquiry into Options for Access to Medicinal Cannabis in Exceptional Circumstances

On behalf of the Australian Lawful Use of Cannabis Alliance ("the Alliance"), I thank you for your invitation to make a submission to the Victorian Law Reform Commission's ongoing 'Inquiry into Options for Access to Medicinal Cannabis in Exceptional Circumstances' ("the Inquiry"). Please find enclosed the Submission of the Australian Lawful Use of Cannabis Alliance.

The Alliance is committed to achieving comprehensive cannabis law reform throughout Australia, which encompasses industrial, domestic, medicinal and recreational uses. Whilst we advocate for more comprehensive reforms than those contemplated by this Inquiry's 'Term of Reference', we believe that compassionate access to cannabis treatments is sorely needed and long overdue in Australia.

We commend the Victorian government for their bold endeavour to provide the potential remedies of cannabis to the sick and ailing in our community that it could help, and we thank the Victorian Law Reform Commission for its thoughtful and diligent handling of the Inquiry to date.

We hope that our Submission assists the Inquiry. We are most happy to assist the Victorian Law Reform Commission in any further way in respect of the Inquiry.

Best regards,

Michael Hislop
President
Australian Lawful Use of Cannabis Alliance

Introduction

Cannabis Law Reform is the legal issue of the decade.

All around the world, communities and their governments are grappling with the legal and political issues connected with overturning the almost century-old prohibition of cannabis. The list of countries that have re-legalised cannabis to some degree, or who are preparing to do so, includes: Uruguay, U.S.A. (23 states of re-legalised access to medicinal cannabis and 4 states and Washington DC have re-legalised recreational access to cannabis), the Netherlands, Portugal, Finland, Czech Republic, Jamaica, Italy, Israel and others.

And, the push for cannabis law reform has now reached Australia.

Throughout Australia, the various Commonwealth, State and Territory governments are pursuing a coordinated process of cannabis law reform. As per agreements made at the Council of Australian Governments meeting in October 2014, the Commonwealth has drafted, and is in the process of debating and deciding, on the *Regulator of Medicinal Cannabis Bill 2014 (Cth)*. New South Wales has taken the lead in organising the conduct of Australian-resident clinical trials concerning the medical efficacy of cannabis in respect of several indicators, and has established the Centre of Cannabinoid Research. Victoria has also commenced this 'Inquiry into Options for Access to Medicinal Cannabis in Exceptional Circumstances', and there is similar activity in the other States and Territories of Australia.

In our opinion, it is long past time that Australian governments legislated to provide for access to the potential benefits and remedies offered by medical cannabis treatments. We recognise that cannabis law reform is a complex undertaking. It necessarily involves making changes to many multi-faceted and interconnected areas of human life (law, healthcare policy, politics, etc.). It is therefore appropriate that the processes that inform cannabis law reform in this country are conducted rationally, thoughtfully and without undue haste.

Having said that, for many people, the continuing delay in providing lawful access to medical cannabis treatments, which in many cases is a proven potential remedy for their sickness and/or solace for their suffering, is unconscionable.

This unconscionable state of affairs is compounded by the fact that the prohibition of cannabis was enacted without regard to rational policy-making principles. It was not enacted following a new scientific discovery or new medical evidence derived from extensive clinical trial. Despite over 10,000 years of use by humans for industrial and domestic purposes, and over 4000 years of use by humans for medicinal purposes, it was proscribed in the U.S.A. Its proscription was then propagated throughout the world in furtherance of American national security objectives.

The result of the prohibition of cannabis is the furtherance of human suffering in our communities. In a very real ways, people are dying every day from ailments that could respond positively to cannabis treatments, and really sick people who are suffering from extreme pain and other really unpleasant symptoms, are being denied access to a potential solace.

The story of one of our members, Ms. Debra Lynch, perfectly encapsulates this tragic saga being played out in our communities. Debra suffers from an incurable illness called Raynaud's Phenomenon with Limited Scleroderma and Gastrointestinal Involvement. She is allergic to every available conventional pharmaceutical treatment option. The only therapeutic treatment that she can tolerate is a course of medical-grade cannabis oil. Like many of our members, and the members of the Medical Cannabis Users Association of Australia, she is daily faced with the unconscionable choice of unlawfully accessing the only available treatment for her condition and its symptoms.

Leaving aside for the moment, the wider philosophical debates about the proper extent that governments should be interfering in individual choices, our vision of Australian society does not involve the criminal sanctioning of individuals for actions done in pursuit of solace of their suffering and remedy for their sickness, nor similar actions done by their carers. It is a sad fact, that thousands upon thousands of ordinary Australians have been deemed criminals by our society for no reason other than this.

The recent tragic experience of one of our members, Mr. Adam Koessler, is a sad example of this…He is currently facing criminal charges and family court proceedings for administering cannabis oil to his daughter who has terminal cancer and is undergoing a long process of chemotherapy.

It is our view that the legal prohibition of cannabis is unjust, in that it leads to unnecessary and unconscionable harm in our communities. We commend the Victorian government on its commitment to rectifying this historical injustice, and we thank the Victorian Law Reform Commission for their thoughtful and diligent handling of this ‘Inquiry into Options for Access to Medicinal Cannabis in Exceptional Circumstances’ (“the Inquiry”) to date.

Comment on the Regulatory Objectives Identified in the Issues Paper by the Victorian Law Reform Commission (Question 7)

The Alliance acknowledges the 6 regulatory objectives set-out by the Victorian Law Reform Commission in its Issues Paper.

We whole-heartedly endorse the need for, and the underlying intention of the Victorian government, to legislate to provide avenues for access to medical cannabis treatments for those who must need it and would most benefit from it.

We concur with their expressed commitment to ensure that any resultant legislation provides the most appropriate avenues for accessing medicinal cannabis treatment options. We agree that this would involve making available the fullest range of safe medical cannabis treatment options, and ensuring that when availed of, they are properly integrated into a patient's treatment plan. It is our hope that cannabis medicine will once again return to mainstream pharmacology, and in so doing provide an impetus towards the development and delivery of a more patient-centred and self-determining form of healthcare.

Our conception of cannabis treatment options as a part of a more patient-centred and self-determining form of delivering healthcare in this country is predicated on the notion of informed individual choice. Informed individual choice, coupled with oversight by a tailored regulatory regime composed of appropriate safeguards against potential harms associated with poor quality, unsafe methods of consumption, and long-term abuse. Implicit in the notion of a tailored regulatory regime composed of appropriate safeguards, is making systemic allowance for changes in the state of clinical knowledge concerning the medical efficacy of cannabis, and the incentivising of scientific research into related topics.

Whilst we recognise and accept as important the imperative to prevent the encroachment of the illicit market providers during the transition to a legal medical cannabis industry in Australia, we disagree with the continuation of the enforcement of the prohibition of cannabis. Not only has it been ineffective in eliminating cannabis consumption in our communities, its continuation is propagating human suffering and causing economic damage in our communities. Furthermore, thousands upon thousands of ordinary Australians are being made criminals in the eyes of our laws, solely for seeking access to the potential remedy and solace offered by cannabis.

These people are not criminals in our eyes. Nor in our opinion should they be typified as such by our laws. In our opinion the continuation of the prohibition of cannabis is unjust. American founding father Thomas Jefferson famously said "*When injustice becomes law then resistance becomes a duty.*"

Our political system is underpinned by notions of individual rights to make those choices that are best suited to themselves and their chosen lifestyle and objectives. Indeed, modern society is largely the product of bloody battles to carve out these rights for individuals.

Furthermore, a central notion of our legal system is the principle that our laws should change to accommodate changed community values and new scientific understandings. There is no better example of this, than the present international trend of cannabis law reform. This point was made perfectly by Canadian Provincial Court Judge J Challenger in delivering a recent Judgment in which she completely discharged a man for cultivating 414 cannabis plants, "*When it becomes common for persons of good character to willingly and knowingly conduct themselves in violation of a law, which is widely seen to be unwarranted or unjust, or unfair, this should cause those who enact our laws and who are tasked with enforcing or upholding the law to give serious consideration to the repeal or amendment of that law to bring it into accord with modern social values...*"[1]

On this basis, we ask the Victorian Law Reform Commission ("the Commission") to reconsider its commitment to the continued enforcement of the prohibition of cannabis in Australia. We recommend that the Commission instead express a firm commitment to affirming and articulating the rights of the individual in safely accessing medicinal cannabis and integrating it into their overall treatment plan and attendant lifestyle choices.

Comment on the Effectiveness of Creating of a Defence to Prosecution for Authorised Patients and Carers in Possession of Small Amounts of Dried Cannabis or Cannabis Products (Question 8)

It is the Alliance's position that the prohibition of cannabis is unjust because it is causing human suffering and economic damage in our communities. Furthermore, it is perversely criminalising thousands upon thousands of ordinary Australian's whose only action is to seek remedy for their ailments, and solace for their suffering.

It is our submission that this is not the intended aim of our criminal justice system, nor the intent of Australian governments.

Creating a defence for criminal prosecution in respect of personal possession of cannabis will not right the historical injustice of the prohibition of cannabis, nor would it rectify and prevent its unintended consequences. It also would not provide a safe and consistent system of access to medicinal cannabis treatments.

[1] R v Santos, 2014 BCPC 266 (CanLII)

For What Conditions/Symptoms is There Sufficient Knowledge to Justify Access? (Question 2)

It is our submission that the starting point for any Inquiry into appropriate regulatory options for access to medicinal cannabis, must be, the list of conditions for which there is evidence of therapeutic effect and other benefit. Before contemplating models for regulating access to medicinal cannabis, it is rational and necessary to first establish the existence of evidence and/or indications of any therapeutic effects and benefits.

This is a difficult task in respect of cannabis, because there is a scarcity of existent information to the requisite standard, about the nature of cannabis and its therapeutic and other effects. What information that does exist, is often incomplete or faulty, due to poor research design and small sample sizes.

The near-century old prohibition of cannabis has done its job well. Much of the public discourse concerning cannabis, its nature and its effects, is best described as "Fears", as opposed to facts. Further, research funding into the nature and effects of cannabis has been severely limited through its linkages to the goals of the Commonwealth's National Drug Strategy.[2]

Furthermore, the uneven pace of cannabis law reform in many jurisdictions has meant that certain parts of cannabis are being reclassified and in essence re-legalised, whilst others remain significantly legally proscribed. An example of this is the recent Interim Decision to re-classify of one of the cannabis plant's active ingredients, namely cannabidiol, on the Commonwealth administered Poisons Standard.[3] This is at odds with a significant body of evidence, known as the "Entourage Effect", which suggests that the therapeutic value of cannabis is intimately related to the interactions of all its chemical ingredients in concert.[4]

The practical effects of the current prohibition of cannabis and the uneven pace of cannabis law reform, is the prioritizing of research only into certain parts of the cannabis plant. Commercialization of cannabis medical treatments is likewise necessarily being channelled into delivering a limited ranged of therapeutic cannabis products.

The effects of this on the state of clinical knowledge concerning the medical efficacy of cannabis are pronounced. At this stage, it is difficult to make pronouncements that there is a settled body of scientific and medical evidence about the medical efficacy of cannabis in respect of most conditions. This fact was elucidated well in the Commission's Issues Paper, where it quoted Fitzcharles et al, "*Simply acceding to patient demands for a treatment on*

[2] National Drug Strategy: 2010 – 2015 (Cth)
[3] '*Reasons for Scheduling Delegates Interim Decision and Invitation for Further Comment for the ACMS, February 2015'*, Therapeutic Goods Administration, 5 February 2015
[4] Russo, E. B. '*Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects'*, British Journal of Pharmacology (August 2011) 163 (7), pp 1344-1364

the basis of popular advocacy, without comprehensive knowledge of an agent, does not adhere to the ethical standards of medical practice ... any recommended therapy requires proof of concept by sound scientific study that attests to both efficacy and safety."[5]

Rather than a firm body of scientific evidence that identifies and illuminates all of the benefits, risks, dangers and side-effects associated with the use of cannabis treatment options in respect of most conditions, we have a growing collection of positive indications of therapeutic value in respect of a staggeringly large array of medical conditions.

Despite this, research commissioned and completed specifically in the last three years, is providing a more rigorous body of evidence concerning the medical efficacy of cannabis. For example, a recent study conducted by the Technion-Israel Institute of Technology in Haifa, Israel that has been examining the effects of dozens of strains of cannabis plants in respect of treating hundreds of types of cancer, reported "*There is a large body of scientific data which indicates that cannabinoids specifically inhibit cancer cell growth and promote cancer cell death…In addition to active cannabinoids, cannabis plants also contain a multitude of other therapeutic agents, such as terpenoids and flavonoids that are usually present in small quantities, but can have beneficial therapeutic effects, especially as synergistic compounds to cannabinoids.*"[6]

Accordingly, at this time it is most accurate to create two lists of conditions for which there is a body of scientific and medical evidence concerning therapeutic efficacy of cannabis treatment options. "List 1" would comprise those conditions and/or symptoms of which there is a significant and settled body of scientific and medical evidence to the requisite standard. "List 2" would comprise those conditions and/or symptoms for which there are a number of positive indications concerning the therapeutic value of cannabis, either by way of existing scientific and medical evidence that are in some way deficient by way of poor design or small sample size, authorisation for that condition/treatment in another jurisdiction, or is currently being investigated through scientific study in this jurisdiction or another.

Whilst an exhaustive exposition of the state of clinical knowledge concerning the medical efficacy of cannabis is impossible here, given time and space constraints, one of the Alliance's objectives is to collect and collate the existing scientific and medical evidence concerning the medical efficacy of cannabis. On this basis, we submit the following non-exhaustive Lists of conditions/symptoms for the Commission's consideration.

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[5] '*Medical Cannabis Issues Paper*', Victorian Law Reform Commission, (March 2015)

[6] Efrati, I. "*Preliminary Results from Israeli Study: Cannabis Delays Cancer Development"*, Haaretz, 11 April 2015, available at http://www.haaretz.com/life/health-fitness/.premium-1.651249

List 1 – Conditions/Symptoms for which there exists a significant and settled body of scientific and medical evidence concerning the therapeutic value of cannabis treatment options:

- Cancer
    - Breast Cancer
    - Bowel, Colon and Colorectal Cancers
    - Brain Cancer
    - Mouth and Throat Cancer
    - Lung Cancer
    - Bladder, Uterine, Testicular and Pancreatic Cancers
    - Biliary Tract Cancer
    - Liver Cancer
    - Skin Cancer
    - Some of the Blood Cancers
    - Ovarian Cancer
    - Prostate Cancer
- Seizures associated with Epilepsy and other severe neurologically disorders, like:
    - Dravets Syndrome
- Spasticity associated with Multiple Sclerosis
- Crohns Disease
- Arthritis
- Analgesia
- Anti-emesis
- Alzheimer's Disease and certain types of Dementia
- Glaucoma
- As a co-agent in cyto-therapies
- Appetite stimulation

List 2 – Conditions/Symptoms for which there are a number of positive indications concerning the therapeutic efficacy of cannabis treatment options:

- Post-Traumatic Stress Disorder
- Anxiety and Depression
- Autism
- Diabetes
- Eczema and Psoriasis

Aside from the above Lists, we ask the Commission to consider the fact that cannabis medical treatments also offer significant preventative and protective benefits against the development of many common illnesses and ailments. Examples include: as an anti-fungal agent, and as an anti-inflammatory agent. Another important example is the prevention of

the build-up of damaging proteins which can be a precursor to the onset of Alzheimer's Disease and some other types of Dementia.[7] Dr. Ethan Russo, in a famous study on Clinical Endo-Cannabinoid Deficiency, has also noted that the cause of many common human ailments is related to deficiencies or imbalances in the levels of the body's own endogenous endo-cannabinoids, and that the cannabinoid compounds that occur naturally in the cannabis plant can effectively assist and augment the body's endo-cannabinoid system. He reported "*Deficient cannabinoid levels may be the underlying cause of numerous conditions alleviated by cannabis.*"[8]

On this basis, we seek the widest possible definition of "medicinal cannabis" in any resultant legislation in Victoria. Given these potential protective and preventative benefits of medical cannabis treatment options, we ask the Commission why only the sick should have access to medicinal cannabis?

One final matter that we ask the Commission to consider is the fact that hundreds of thousands of ordinary Australians consume cannabis on a regular basis. This community in Australia, is often misunderstood, and is almost always overlooked in the public debate concerning cannabis law reform. Their consumption of cannabis is best understood as a subset of medicinal cannabis usage, in that most are consuming cannabis to access its natural relaxant and anxiolytic effects. This point was perfectly encapsulated by the same Canadian Provincial Court Judge J Challenger who held "*…Even if the only benefit the use of marijuana actually provides is hope, the emotional and, in turn, physical benefits could well be medically significant…*"[9]

What Should Constitute "Exceptional Circumstances"? (Question 1)

It is the stated aim and objective of the Alliance, to achieve comprehensive cannabis law reform throughout Australia, which encompasses and provides for domestic, industrial, medicinal and recreational uses. It is our submission that cannabis medical treatment options offer both therapeutic benefits, as well as potential protective and preventative effects. It is our further submission that cannabis medical treatments should be widely available and easily accessible, subject to certain stringent safeguards against misuse, abuse, quality, and safety of consumption.

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[7] Eubanks et al, 'A Molecular Link Between the Active Component of Marijuana and Alzheimer's Disease Pathology', Molecular Pharmaceutics, (2006) 3 (6), pp. 773-777

[8] Russo, E. B., *'Clinical Endocannabinoid Deficiency (CECD): Can This Concept Explain Therapeutic Effects of Cannabis in Migraine, Fibromyalgia, Irritable Bowel Syndrome and Other Treatment Resistant Conditions?*' Neuroendocrinology Letters, (February/April 2004), Vol. 25, Nos 1/2

[9] R v Santos, 2014 BCPC 266 (CanLII)

We acknowledge that this is opposite to this Inquiry's Terms of Reference, which stipulate that the Commission only make Inquiry into options for access to medicinal cannabis in "exceptional circumstances". Accordingly, we refrain from making extensive further comment on the matter, except to make the following two observations.

Firstly, we ask the Commission to recognise that the reason the Terms of Reference are narrowly framed and limited to "exceptional circumstances", is because of the long-standing prohibition of cannabis. We ask the Commission to further recognise that Prohibition is a policy which has failed on its own terms, and which we respectfully submit is unjust because it is causing human suffering and economic damage in our communities. Respectfully, it is our position that it would have been more ideal for the Commission to have been authorised under its 'Terms of Reference' to inquire more broadly as to "what circumstances" justify access to cannabis and derivative products.

Second, it is our submission, that Victoria's eventual 'Medical Cannabis Access Scheme' should base determinations of a person's eligibility to access medicinal cannabis on two guiding principles: "Need" and "Choice".

Determining Eligibility to Access Medicinal Cannabis in Exceptional Circumstances (Question 4)

As stated previously, it is our position that cannabis medical treatments should be widely available and easily accessible, subject to certain stringent safeguards against misuse, abuse, quality, and safety of consumption. Accordingly, we submit that the process for determining a person's eligibility to access medicinal cannabis under any eventual Victorian 'Medical Cannabis Access Scheme', should have a similarly broad scope.

It is our further submission that Victoria's eventual 'Medical Cannabis Access Scheme' should base determinations of a person's eligibility to access medicinal cannabis on two principles: "Need" and "Choice".

Our conception of "Need" in this context refers to a valid and verifiable medical, health or lifestyle reason for considering access to cannabis medical treatment options.

Our conception of "Choice" in this context refers to informed choices made by individuals, or loved ones who care for them, about their specific medical, health and lifestyle matters. Informed choice in this context means a decision made in concert with, and as part of an ongoing relationship with, a person's healthcare professionals, and as part of an ongoing treatment plan.

Whilst we advocate for a process of determining eligibility that has the broadest possible scope, we submit that access to medical cannabis treatment options is only properly mediated by healthcare professionals as part of an ongoing treatment program. This means that, in our opinion, determining eligibility to access medical cannabis treatment options is the proper domain of healthcare professionals.

This fits with the existing legal regimes concerning cannabis, access to "therapeutic goods", and the classification of drugs and poisons under existing Commonwealth and Victorian laws. Under this current legal framework, access to cannabis medical treatment options will necessarily be via a prescription written by an authorised healthcare professional.

Comment on the Need for Special Considerations to Justify Access to Medicinal Cannabis for Young Persons and those Lacking Legal Capacity (Question 3)

In keeping with our position that determinations of eligibility to access medicinal cannabis is the proper domain of healthcare professionals, we submit that there should be no legislative restrictions or requirements stipulated solely regarding access by children and those lacking legal capacity.

We submit instead that there is a strong legal argument that children, their carers, and those lacking legal capacity, deserve and require easier avenues of access to cannabis medical treatments, as part of an integrated treatment program. Article 25 of the Universal Declaration of Human Rights provides that:
"1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection."[10]

This argument is made stronger by the fact the some of the most pronounced therapeutic effects of medical cannabis treatments, are observed in the treatment of the extreme and involuntary seizures experienced by many young children who suffer from a range of serious neurological disorders (i.e.: Dravets Syndrome). The effect of administering extracted cannabis oils, in measured doses, to many of these persons is measurably significant. The author has spoken to a number of parents of previously very ill children who had turned to cannabis treatment as a last resort, and whose children have now ceased daily seizures, and have over time regained motor function and speech function, and been able to start to school. This is why so many of the people who are leading the Movement for the Re-

[10] *United Nations' 'Universal Declaration of Human Rights' (1948)*

legalisation of Cannabis in Australia are the parents and carers of sufferers of these sorts of incurable and debilitating illnesses.

Having said that, the Alliance is very cognizant that mediating delivery of cannabis medical treatments to children and those lacking legal capacity is necessarily a complex endeavour. It requires specialist skills and long experience in the field. Accordingly, it is probably necessary that only certain types of healthcare practitioners, being specialists in those areas of medicine, be permitted to authorise access to medicinal cannabis to children and those lacking legal capacity.

Comment on the Need for Additional Restrictions/Requirements that Should Apply to "Vulnerable" Patients in Respect of their Access to Medicinal Cannabis (Question 15)

It is our submission that there are three types of "vulnerable" patients who will access medicinal cannabis under any eventual 'Medical Cannabis Access Scheme'. They are:
1) Minors – persons under eighteen years of age;
2) Those lacking legal capacity; and,
3) Patients at high-risk of dependency.

It is our further submission, that the legal distinction of each of these categories of "vulnerable" patients is that they each require some form of further consent, other than that of the individual involved, to access medical cannabis treatments.

Accordingly, any eventual 'Medical Cannabis Access Scheme' in Victoria, should stipulate the forms of further consent acceptable under the scheme. In practice this means:

1. Ensuring and recording parental, or primary care-giver, consent for minors;
2. Providing a simple and transparent process whereby those lacking legal capacity can seek access to medical cannabis treatments; and,
3. Ensuring that individuals, who are deemed by their doctor to be at a high-risk of dependency, receive appropriate guidance on consumption, and information on accessing appropriate social service providers. This can likely be done by giving a standard information leaflet to each person who accesses medicinal cannabis.

It is also likely the case, that only certain medical cannabis treatment options are appropriate for children, and/or other "vulnerable" persons. Having said that, it is our position that determinations of the appropriateness of specific treatment options, is best arrived at by a qualified healthcare practitioner in consultation with and consideration of the wishes of his/her patient, or their carer where necessary and appropriate.

Specific Mechanism to Allow Access for Special Cases (Question 5)

If the Victorian government accepts our submission that determinations regarding a person's need for and thus eligibility to access medicinal cannabis treatment options is the proper domain of prescribing healthcare professionals, a specific mechanism providing for "special cases" would be unnecessary.

Which Healthcare Professionals Should have Authority to Assess Eligibility to Access Medicinal Cannabis? (Question 13)

Cognizant of the constraints of the existing legal framework concerning cannabis and access to therapeutic goods, we have earlier submitted that access to medicinal cannabis treatments should be mediated by authorised healthcare professionals via prescription. Likewise, we submit that Victoria's eventual 'Medical Cannabis Access Scheme' should delineate authority for assessing eligibility for access to registered healthcare practitioners who have prescribing entitlements.

It is our recommendation, that Victoria establish a register of healthcare practitioners who intend to provide medical cannabis treatments ("the Register"). It is our further recommendation that entry on this Register, has as a pre-requisite, the annual completion of a continuing professional education program specifically related to cannabis medicine and/or cannabis medical treatment options.

Responsibilities of Health Practitioners When Authorising Access to Medicinal Cannabis (Question 12)

Healthcare practitioners already have significant and onerous responsibilities to each of their specific patients. It is our submission that the provision of cannabis medical treatments to patients does not require the legislative stipulation of additional responsibilities.

Rather than additional responsibilities, it is our submission that healthcare practitioners involved in the delivery of cannabis medicine need to be priorly informed of the nature and effects of cannabis, and the range of available medical cannabis treatment options.

Given the rapidly changing state of the body of clinical knowledge concerning the medical efficacy of cannabis, they would also likely need access to regular updates to this body of clinical knowledge. This could be done through existing continuing professional education programs, and should be an ongoing requirement of entry on a Victorian Register of healthcare practitioners who intend to provide cannabis medical treatments.

This is a crucial point because, in concert with dispensing entities, these healthcare practitioners will be ultimately responsible for ensuring that people are making informed choices about accessing cannabis medical treatment options.

Comment on What Requirements/Restrictions/Guidance/Other Assistance Health Practitioners should be Given in Monitoring a Patient's Use of Medicinal Cannabis? (Question 14)

It is the Alliance's position that healthcare is best provided by those professionals who are properly trained and licensed to so, acting in concert with and according to the instructions of their patients. In this way, healthcare outcomes can be achieved that best suited for each patient, and that are in-line with their lifestyle choices and aims, and public health objectives.

Accordingly, we submit that legislative provisions that set arbitrary requirements or restrictions on the provision of cannabis medical treatments, may lead to non-optimal healthcare outcomes.

Having said that, healthcare practitioners involved in the delivery of medical cannabis treatments to patients will likely need to be assisted in their task by a dynamic body of Guidelines relevant to each condition. The key question is who should be tasked with developing and propagating these Guidelines?

Comment on Permissible Forms of Medicinal Cannabis (Question 16)

Cannabis is a herbaceous plant originally native to Central Asia, but now grown throughout the world.[11] According to the Integrated Taxonomic Information System, cannabis plants are generally divided into two distinct subspecies: Cannabis Sativa and Cannabis Indica.[12]

Cannabis plants produce a resin containing a combination of psychoactive and non-psychoactive compounds, called cannabinoids. The highest concentration of these cannabinoids is found in the female flowers of the cannabis plant.[13]

[11] Kavasilas, A., *'Medical Uses of Cannabis: An Australian Research Guide to Scientific Findings on The Medical Use of Cannabis'*, (May 2004)

[12] For more information about the Integrated taxonomic Information System's Treatment of cannabis visit http:/www.itis.gov

[13] Adams, I. B. and Martin, B. R. *'Cannabis: Pharmacology and Toxicology in Animals and Humans'*, Addiction Vol 91, No. 11 (1996), pp 1585-1614

There are thousands of breeds or strains of cannabis plants, each with their own unique combination of cannabinoids.

Further, cannabis plants can be processed into a range of products and derivatives. This range of products and derivatives includes:

- Dried raw cannabis flowers and leaves;
- Collected resin or “hashish”;
- Concentrated cannabinoid oils, and,
- Extracted and refined cannabinoids.

These products and derivatives have a multitude of consumption methods. The most common of which are:

- Combusting the material and inhaling the smoke;
- Vaporising the material and inhaling the vapour;
- Preparing the essential cannabinoid oils into an alcohol-based tincture; and,
- Cooking and eating it in various preparations from butter to cakes and cookies.

Methods of medical cannabis treatment, which are used in places throughout the world, include:

- Raw cannabis flower preparations;
- Synthetic cannabis preparations, comprising mainly cannabidiol and tetrahydrocannabinol;
- Pharmaceutical tablets/capsules;
- Oro-mucosal sprays;
- Nano-technology delivery devices;
- Suppositories;
- Tinctures; and,
- Topicals.

It is certainly the case that there is an intimate relationship between the cannabis strain employed, the method of delivery, and the therapeutic efficacy of medical cannabis treatment options. That being so, it is our submission that qualified healthcare practitioners are best suited to determining the most effective form, and amounts thereof, of medicinal cannabis for a particular patient in respect of their specific condition and its symptoms.

We suggest that it is perhaps premature to attempt to articulate the full range of permissible forms of cannabis appropriate in medical treatments, given the present dynamic state of the body of clinical knowledge concerning the medical efficacy of cannabis treatments.

It is also perhaps unnecessary given the central role of the Commonwealth, and its agency – the Therapeutic Goods Administration, in evaluating and approving therapeutic goods and prescription medicines throughout Australia.[14] Furthermore, such an enumeration may be confusing and contradictory, if as expected, the *Regulator of Medicinal Cannabis Bill 2014 (Cth)* is enacted and assented to this year. This Bill proposes the establishment of a Commonwealth Regulator of Medicinal Cannabis, who will develop and maintain a Register of Medicinal Cannabis Products, which it approves.[15]

Comments on How a Victorian 'Medical Cannabis Access Scheme' should Interact with Existing Commonwealth Legislation Proscribing Cannabis (Question 11)

The Commission has identified in its Issues Paper the multi-layered framework of Commonwealth and Victorian laws that interact to proscribe cannabis and sanction its unlawful production and consumption. The Commission clearly understands the complexities that underpin unilateral action by the Victorian government in respect of cannabis law reform.

We agree with the Commission's assertions that extensive consultation and close cooperation between the Commonwealth and the State of Victoria, is necessary to ensure that any legislation providing for a 'Medical Cannabis Access Scheme' in Victoria, is workable and suited to achieve its stated purposes.

It is clear, from the introduction and likely enactment this year of the *Regulator of Medicinal Cannabis Bill 2014 (Cth),* that the Commonwealth intends to have a role in shaping and regulating the emerging medicinal cannabis industry in Australia. From the agreement reached between the Commonwealth and the States and Territories at the Council of Australian Governments meeting late last year, we have a clear picture of the role that the Commonwealth intends to play in this space.

In keeping with its international law obligations under the United Nations' *Single Convention on Narcotic Drugs (1961),*[16] it seeks to establish a national Regulator of Medicinal Cannabis ("the Regulator"), and a nationally applicable process for evaluating and approving medicinal cannabis products.

[14] The role of the Commonwealth in evaluating and approving therapeutic goods and products is articulated in the *Therapeutic Goods Act 1989 (Cth)* and the *Therapeutic Goods Regulations 1990 (Cth)*.
[15] *Regulator of Medicinal Cannabis Bill 2014 (Cth)*
[16] United Nations' *Single Convention on Narcotic Drugs* (1961)

However, it is presently unclear the extent to which the Commonwealth intends to repeal or amend its other legislation, which classifies cannabis as a dangerous poison, and attendant criminal sanctions for its unlawful production and consumption.

Comments on How the Victorian 'Medical Cannabis Access Scheme' Should Interact with the National Arrangements for the Control of Therapeutic Products under Therapeutic Goods Legislation and Narcotic Drugs Legislation (Question 6)

Cognizant of the role being currently appropriated by the Commonwealth in respect of regulating medicinal cannabis, we wish to point out the important aspects of regulation left to the States and Territories.

In keeping with the separate responsibilities delineated to the Commonwealth and States/Territories in respect of regulating other types of therapeutic products and devices, the Commonwealth through the Regulator intends to be the central actor in evaluating and approving medical cannabis products, goods and devices. The States and Territories will be responsible for regulating the sale and distribution of approved medical cannabis products within their respective jurisdictions.

The practical effect of this is that the primary regulatory role for the State of Victoria in respect of medicinal cannabis is the regulation of the cultivation, possession and supply of medical cannabis products within its geographical boundaries. It is our submission that any legislation to be drafted by the Victorian government at the end of this Inquiry should have this as its primary focus.

It is our further submission that in order to achieve the best possible public health outcomes, and to provide the emerging medical cannabis industry the best possible foundation, the following courses of action are necessary, and within the powers of the State of Victoria. We commend them to the Commission for consideration.

1. Petition the Commonwealth Health Minister to reschedule cannabis and all its constituent parts on the Commonwealth's Poison's Standard.
2. Petition the Commonwealth Health Minister to make a declaration that medicinal cannabis goods and products are exempted from the application of the *Therapeutic Goods Act 1989 (Cth)* and the *Therapeutic Goods Regulations 1990 (Cth)*.
3. Petition the Commonwealth for amendments to the Narcotic Drugs Act 1967 (Cth) to exclude from its provisions, the manufacture and production of medicinal cannabis.
4. Work to establish a formal system of consultation between the foreshadowed Regulator of Medicinal Cannabis and the relevant Commonwealth and State and Territory departments and agencies.

5. Petition the FSANZ to approve the consumption of hemp seed and oil as a "food" by humans.
6. Amend the *Drugs, Poisons and Controlled Substances Act 1981 (VIC)* and the *Drugs, Poisons and Controlled Substances Regulations 2006 (VIC)* to remove the legal penalties associated with unlawful use of cannabis.
7. Provide a legal amnesty to those persons who have been criminally sanctioned for seeking access to medicinal cannabis.
8. Enact a Victorian Bill that enables access to medical cannabis treatments where deemed appropriate by authorised healthcare professionals.

Comments on What Mechanism Victoria Should Use to Regulate the Cultivation of Medicinal Cannabis (Question 9)

Given the likelihood of the enactment of the *Regulator of Medicinal Cannabis Bill 2014 (Cth)* and the attendant establishment of the nationally-applicable Regulator of Medicinal Cannabis, we hold concerns that a similarly concerned Victorian Act would inevitably comprise of duplicate and perhaps contradictory regulations concerning the cultivation of medicinal cannabis.

Comments on What Approach Victoria Should Take to Regulating how Medicinal Cannabis is Processed and Distributed (Question 10)

As we pointed out previously, the central regulatory role for the State of Victoria is respect of medicinal cannabis, is in respect of its distribution and supply within its geographical boundaries.

To do this, Victoria needs to develop a system that addresses and provides for the following:

- Licensing system for distributors and vendors of medicinal cannabis in the State of Victoria;
- A system of rules and regulations that address the issues about where distributors and vendors of medicinal cannabis can conduct their business; and
- A system of rule and regulations about the conduct of their business.

Victoria will also need to consult closely with the Commonwealth about the possible role of constitutional corporations in delivering medicinal cannabis products and treatments in its jurisdiction. The author notes that these issues will likely be resolved with the enactment and assent of the *Regulator of Medicinal Cannabis Bill 2014 (Cth)*.

The Alliance anticipates a role for a large range of types of legal entities in the distribution and delivery of medicinal cannabis products and treatments, including: partnerships, constitutional and non-constitutional corporations, cooperatives, non-profit associations, charities, and trusts.

How Victoria's 'Medical Cannabis Access Scheme' could Contribute to, Clinical Research into the Therapeutic Uses of Cannabis and Other Changes in Scientific Knowledge, Medical Practices and Technology (Question 17)

The Alliance concurs with the Commission's position that any model for access to medicinal cannabis that is developed in Victoria be amenable to adjustment as the state of relevant research knowledge requires.

In our opinion, this is exceedingly important given the present dynamic state of the body of clinical knowledge concerning the applicability and medical efficacy of cannabis treatment options. It is likely that as cannabis law reform becomes the norm, and as the prohibition of cannabis is steadily repealed throughout the world, significant additions to the body of clinical knowledge concerning cannabis will be made.

Accordingly, legislative systems of access to medicinal cannabis like that being presently considered by Victoria, need to have a systemic mechanism for accommodating those changes to the body of clinical knowledge concerning medicinal cannabis.

We suggest to the Commission, that these objectives can be met by providing a systemic mechanism that gives the eventual Victorian state agency rule-making powers as part of a regular process of review and consultation with the public and key stakeholders.

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